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(54) Disposable delivery device for endoluminal protheses

(57) Improved systems, devices, and methods for deployment of endoluminal prostheses (10) within the lumens of the body, and particularly for deployment of stents and stent-grafts within the vascular system. Optionally a sheath (32) is withdrawn from over a tightly compressed prostheses (10) using an actuation mechanism having a variable mechanical advantage, which varies with the position of the sheath. The handle (52) for the actuation mechanism may rotate about an axis parallel to the axis of the sheath (32). The deployment systems of the present invention will preferably include a "one-way" rotation mechanism, thereby avoiding any inadvertent counter-rotation of the handle (52) causing undesirable movement of the prosthesis or delivery system (30).

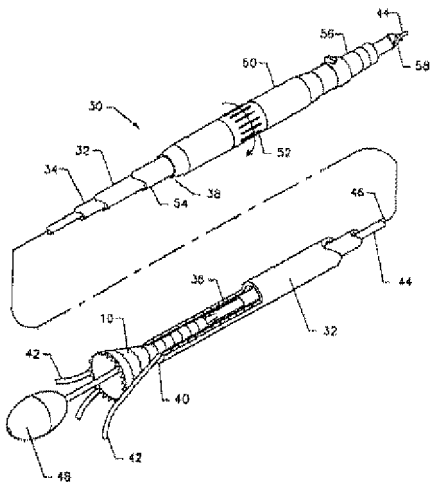

FIGURE 2

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention provides improved delivery systems and methods for their use to accurately and safely deploy endoluminal prostheses within the lumens of the body, particularly within the vascular system for treatment of aortic aneurysms, stenoses, and the like.

[0002] Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease and/or genetic predisposition, which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, with the majority of aortic aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending into one or both of the iliac arteries.

[0003] Aortic aneurysms are now commonly treated in open surgical procedures where the diseased vessel segment is bypassed and repaired with an artificial vascular graft. While considered to be an effective surgical technique, particularly considering the alternative of a usual fatal ruptured abdominal aortic aneurysm, conventional vascular graft surgery suffers from a number of disadvantages. The surgical procedure is complex and requires experienced surgeons and well-equipped surgical facilities. Even with the best surgeons and equipment, however, patients being treated frequently are elderly and weakened from cardiovascular and other diseases, reducing the number of eligible patients. Even for eligible patients prior to rupture, conventional aneurysm repair has a relatively high mortality rate, usually from 2% to 10%. Morbidity related to the conventional surgery includes myocardial infarction, renal failure, impotence, paralysis, and other conditions. Additionally, even with successful surgery, recovery takes several weeks, and often requires a lengthy hospital stay.

[0004] In order to overcome some or all of these drawbacks, endovascular prosthesis placement for the treatment of aneurysms has been proposed. Although very promising, many of the proposed methods and apparatus suffer from undesirable limitations. In particular, accurate delivery and placement of the endovascular prosthesis within the vasculature can be problematic.

[0005] Stent-grafts are often resilient structures, biased to expand against the surrounding lumenal wall. Such resiliently-expanding stent-grafts are tightly compressed within the catheter, imposing significant forces against the surrounding catheter sheath. This can often lead to excess friction between the stent-graft and the sheath, particularly when the resiliently-expanding structure invaginates into the catheter material. As these catheters are often required to maneuver within the tortuous vascular system, catheter sheaths are often formed as flexible, elongate bodies which are particularly susceptible to invagination of the tightly compressed stent-graft in the flexible material of the catheter wall.

[0006] For these reasons, it would be desirable to provide improved devices, systems, and methods for endoluminal deployment of prostheses such as stents, stent-grafts, and the like, for treatment of aneurysms and other diseases of the body lumens. It would be particularly desirable if such improved systems and methods enhanced the accuracy and safety of the deployment procedure, without significantly increasing deployment time, equipment costs, or complexity of the deployment procedure.

2. Description of the Background Art

[0007] Devices for endoluminal placement of prostheses are described in U.S. Patent Nos. 4,512,338, 4,651,738, 4,665,918, 5,458,615, 5,480,423, 5,484,418, 5,489,295, 4,990,151, 5,035,706, 5,433,723, 5,443,477, 5,282,824, 5,275,622, 5,242,399, 5,201,757, 5,190,058, 5,104,399, 5,092,877, 4,990,151, and EP Patent Publication Nos. EP 0 539 237 A1, 0 518 839 A2, EP 0 505 686 A1, and EP 0 508 473 A2.

SUMMARY OF THE INVENTION

[0008] The invention is defined in the independent claims 1, 12, 14 and 15. According to preferred embodiments the present invention provides improved systems, devices, and methods for deployment of endoluminal prostheses within the lumens of the body, and particularly for deployment of stents and stent-grafts within the vascular system. Optionally a sheath is withdrawn from over a tightly compressed prostheses using an actuation mechanism having a variable mechanical advantage, which varies with the position of the sheath. Once deployment is safely underway, and after static frictional forces have been overcome, the remainder of the deployment may proceed more rapidly, without significantly degrading overall safety or ease of use. In some embodiments, the handle for the actuation mechanism may rotate about an axis parallel to the axis of the sheath. Regardless, the deployment systems of the present invention will preferably include a "one-way" rotation mechanism, thereby avoiding any inadvertent counter-rotation of the handle causing undesirable movement of the prosthesis or delivery system. Accuracy and ease of use of the delivery system may optionally be improved by providing an outer tube around the sheath which is coupled to the prosthesis restraining member within the sheath. The outer tube may be inserted through an introducer valve, so that friction between the outer tube and introducer valve helps restrain the prosthesis at the target position as the sheath is withdrawn proximally.

[0009] In a first aspect, the present invention provides a delivery system for use with a tubular endoluminal prosthesis. The delivery system includes a sheath having a proximal end, a distal end, and a lumen, which is capable of receiving the prosthesis near the distal end. The system also includes a member, in the lumen of the sheath. The member expels the prosthesis from the lumen as the sheath moves from a first position to a second position relative to the member. The sheath is coupled to a handle using an actuation mechanism which engages the member. Also, included in the system is a uni-directional mechanism operatively associated with the actuation mechanism. The uni-directional mechanism is capable of preventing movement of the sheath toward the first position.

[0010] In yet another aspect, a prosthetic delivery system is provided for use with a radially expandable tubular endoluminal prosthesis. The delivery system includes a sheath having a proximal end, a distal end, an axis therebetween, and a lumen capable of receiving the prosthesis near the distal end. Disposed in the lumen is a member for expelling the prosthesis from the lumen as the sheath moves from a first position to a second position relative to the member. An actuation mechanism is attached to the member and has threads which have a variable thread pitch which also varies along an axis of the threads. The actuation mechanism couples the sheath to a handle, where the handle is rotatable about an axis substantially parallel to the axis of the sheath. The handle effects movement of the sheath from the first position to the second position. The system also includes a ratchet mechanism. The ratchet mechanism includes a resilient member, which has at least one pawl and a serration ring associated with the actuation mechanism. The serration ring engages the at least one pawl in a ratcheting relationship. The resilient member is operative on the at least one pawl and urges the at least one pawl in to the engagement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011]

Fig. 1 is a simplified side view of an exemplary cylindrical vascular stent-graft.

Fig. 2 is a perspective view of a delivery system according to the principles of the present invention.

Fig. 3 illustrates an exemplary modular endoluminal bifurcated prosthesis.

Fig. 4 illustrates a method for using the delivery system of Fig. 2 for deploying a bifurcated prosthetic module.

Fig. 5 illustrates an outer tube for use in the delivery system of Fig. 2 to provide a low-friction seal between an introducer valve and the delivery sheath.

Fig. 6 illustrates a method for using the outer tube between the delivery sheath and an introducer valve to prevent movement of the prosthesis during deployment.

Fig. 7 illustrates an alternative delivery system which prevents relative motion between the introducer valve and the prosthesis with an external support rod.

Fig. 8 is a cross-sectional view showing the actuation mechanism of the deployment system of Fig. 2.

Fig. 9 is an exploded view showing the components of the actuation mechanism of Fig. 8.

Figs. 10 and 11 are a cross-sectional view and a side view, respectively, of an alternative deployment system having an actuation mechanism including threads which vary in pitch.

Fig. 12 illustrates a mandrel for forming variable pitch threads for use in the deployment system of Fig. 10.

Fig. 13 is a cross-sectional view through the actuation handle of the deployment system of Fig. 10.

Figs. 14 through 17 illustrate components of the actuation system for use in the deployment systems of Figs. 2 and 10.

Figs. 18 and 19 are a cross-sectional view and a side view, respectively, of an alternative deployment system having an actuation mechanism including the uni-directional rotation mechanism.

Figs. 20 and 21 illustrate components of the actuation system for use in the deployment systems of Fig. 18.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0012] The present invention provides delivery devices, systems, and methods for delivering radially expandable tubular prostheses, particularly stents, stent-grafts, and the like. The delivery structures and methods of the present invention are suitable for a wide variety of therapeutic uses, including stenting of the ureter, urethra, trachea, branchi, esophagus, biliary tract, and the like. The structures and methods will also be useful for creating temporary or long-term lumens, such as for the formation of fistulas. The present invention will find its most immediate application for delivery of endovascular prostheses as a treatment for diseases of the vasculature, particularly for treating aneurysms, stenoses, and the like.

[0013] The structures and methods described hereinbelow will find use in deployment of axially uniform cylindrical prostheses, of pre-assembled bifurcated prostheses, and of prosthetic modules for selective assembly, either prior to deployment or in situ. Modular prosthetic structures and delivery methods are more fully described in co-pending U.S. Patent Application Nos. 08/704,960, filed August 29, 1996 08/538,706, filed October 3, 1995 and 60/028,928, filed October 7, 1996, the full disclosures of which are incorporated herein by reference.

[0014] The phrase "mechanical advantage," as used

herein, refers to the ratio of the output force of a machine, or other device, to the input force. An advantage is achieved when the ratio is greater than one. This allows movement of the sheath to be initiated with ease and accuracy.

[0015] Referring now to Fig. 1, an exemplary cylindrical prosthesis 10 comprises a preferred tubular frame 12 formed as a plurality of independent ring frames 14. Tubular frame 12 supports an inner liner 18. Optionally, an outer liner is disposed over the ring frames, either inside of inner liner 18, or in combination therewith.

[0016] To secure ring frames 14 to liner 18, the liner is typically sutured to the frame. A wide variety of alternative liner/frame attachment mechanisms are available, including adhesive bonding, heat welding, ultrasonic welding, and the like. Preferably, liner 18 is sutured along the extreme proximal and distal ends of frame 12 to enhance sealing between the liner and the surrounding body lumen.

[0017] Prosthesis 10 will typically have a length in the range from about 20 mm to 500 mm, preferably being 50 mm to 200 mm. A relaxed diameter of prosthesis 10 will generally be in the range from about 4 mm to 45 mm, preferably being in the range from about 5 mm to 38 mm.

[0018] Referring now to Fig. 2, an exemplary delivery system 30 comprises a tubular sheath 32 and a shaft 34. Sheath 32 has a lumen 36 extending from a proximal end 38 to a distal end 40. Shaft 34 is slidably received within lumen 36, and a plurality of runners 42 extend distally from the shaft. Runners 42 line a portion of the inner surface of lumen 36, and slide within the lumen of the shaft. Shaft 34 also has a lumen, in which a core shaft 44 is affixed. Core shaft 44 has a guidewire lumen 46. Nosecone 48 is affixed to the distal end of core shaft 44, and can therefore be manipulated with the runners. Alternatively, core shaft 44 may be slidably disposed within shaft 34 to allow independent manipulation of nosecone 48.

[0019] Prosthesis 10 is radially compressed and restrained within runners 42. In turn, sheath 32 prevents runners 42 from expanding outwardly. Runners 42 are preferably formed from a hard material, and distribute the expansive load from the frame of prosthesis 10 over the inner surface of lumen 36. Exemplary methods and devices for deploying prostheses using runners 42 are more fully described in co-pending U.S. Patent Application Serial No. 08/475,200, filed June 7, 1995, the full disclosure of which is incorporated herein by reference.

[0020] A housing 50 is disposed at proximal end 38 of sheath 32. Housing 50 contains an actuation mechanism for withdrawing sheath 32 proximally while prosthesis 10 is axially restrained by runners 42 and shaft 34. To withdraw sheath 32 proximally, a handle 52 is rotated about the axis of the sheath, as illustrated. This avoids inadvertently imparting any axial movement of the delivery system from rotation of the handle during deployment, preventing prosthesis 10 from being displaced axially from the target location, and also avoiding any injury of the surrounding body lumen by inadvertently advancing runners 42.

[0021] An outer tube 54 extends distally from housing 50 over sheath 32. Shaft 34 extends through housing 50 and is affixed to a connector 56, which is releasably attached to the proximal end of housing 50. Thus, shaft 34 and outer tube 54 are coupled together through the housing, so that sheath 32 retracts proximally between these two structures when handle 52 rotates. Once the prosthesis is deployed and runners 42 slide proximally from between the prosthesis and surrounding body lumen, connector 56 may be uncoupled from housing 50 to draw runners 42 and the proximal portion of nosecone 48 back into the distal end of sheath 32.

[0022] A luer fitting 58 is affixed to the proximal end of connector 56 to facilitate introducing a guidewire into guidewire lumen 46 of core shaft 44, or to allow the guidewire lumen to be sealed when not in use.

[0023] Referring now to Fig. 3, an assembled branching endovascular prosthesis 60 comprises a relatively rigid lumen separation portion 62 between a trunk portion 64 and two branch portions 68. Lumen separation portion 62 may include a contiguous frame to provide relatively high column and hoop strength, while the branch end trunk portions may be formed with independent ring frames or a helical frame in which the loops are separated to enhance axial flexibility. Sealing cuffs 66 and 70 securely anchor the prosthesis against healthy tissue, and also seal the prosthetic lumen against the surrounding endolithium of the blood vessel.

[0024] As schematically illustrated in Fig. 4, a bifurcated prosthetic module of bifurcated prosthesis 60 may be deployed using delivery system 30 to isolate an abdominal aortic aneurysm AAA. This initial prosthetic module extends from the abdominal aorta AA to a first iliac I, and has an open port 72 for receiving a cylindrical prosthetic module to effectively seal the distended aneurysm from the blood flow. The prosthetic module is deployed by axially restraining the module within runners 42 and withdrawing sheath 32 proximally. The runners, which typically comprise thin strips of a high-strength metal such as stainless steel, slide along the inner lumen of sheath 32 and flex outwardly as the prosthesis expends resiliently. Once the prosthetic module is fully expanded, the runners can be withdrawn proximally from between the prosthesis and the surrounding luminal wall, while the expanded prosthesis engages the luminal wall between the runners.

[0025] The bifurcated prosthetic module illustrated in Fig. 4 includes a pattern of discreet radiopaque markers 74 to facilitate positioning and assembly of the prosthetic modules fluoroscopically. The use and structure such radio-opaque markers is more fully described in co-pending U.S. Patent Application Serial Nos. 08/628,797, filed April 5, 1996 and 08/877,151, filed June 17, 1997, the full disclosures of which are incorporated herein by reference.

[0026] Referring now to Fig. 5, outer tube 54 generally comprises a tubular body 76 and an endcap 78. An o-ring 80 is disposed within endcap 78, and provides a low friction hemostasis seal around the outer surface of sheath 32. As described above, the runners of the present invention facilitate smoothly retracting sheath 32 relative to the radially compressed prosthesis. However, a substantial amount of friction may be encountered between the outer surface of delivery system 30 and introducer sheath 82 at which the delivery system enters a patient's body 84.

[0027] Introducer sheaths generally provide hemostasis around catheters, guidewires, other invasive surgical implements of various sizes and configurations. Such introducer sheaths typically include a resilient sealing body which radially engages the outermost layer of the delivery system. As it is generally desirably to leave the internal prosthesis at a fixed position while withdrawing sheath 32 proximally, such friction between introducer valve 82 and sheath 32 is generally disadvantageous. However, by coupling outer tube 54 to housing 50, as illustrated in Fig. 6, and by providing an actuation mechanism which withdraws sheath 32 relative to shaft 34 and housing 50, friction between outer tube 54 and introducer valve 82 may be used to help restrain the prosthesis at the target location during deployment.

[0028] To facilitate insertion of outer tube 54 into introducer valve 82, a distal end of tubular body 76 may be tapered. In some embodiments, introducer valve 82 may be actuated once outer tube 54 and the prosthesis are positioned, compressing the sealing body against the outer tube to lock the prosthesis in place. A particularly advantageous actuatable introducer valve is described in co-pending U.S. Patent Application No. 08/744,659, filed November 6, 1996, the full disclosure of which is incorporated herein by reference.

[0029] An alternative system and method for maintaining the position of the prosthesis within patient body 84 is illustrated in Fig. 7. In this embodiment, the actuation mechanism for withdrawing sheath 32 relative to shaft 34 is contained in a removable actuation housing 86. Housing 86 is coupled to introducer valve 82 using a brace rod 88. Although housing 86 and the actuation mechanism therein may be reused for several deployment procedures, the cost of such a system is generally higher than the delivery system illustrated in Fig. 2, particularly when repeated sterilization of the housing and actuation mechanism are considered. Additionally, the use of an actuation handle which rotates perpendicularly to the axis of sheath 32 may lead to inadvertent axial movement of the prosthesis during deployment. This can be particularly problematic when runners 42 are exposed about the perimeter of the body lumen, as any distal advancement of the runners may lead to injury or penetration through the luminal wall.

[0030] An actuation mechanism 90 which converts the axial rotation of handle 52 to axial translation of sheath 32 can be understood with reference to Figs. 8 and 9. Handle 52 comprises a tubular structure having internal threads 92. Housing 50 includes a distal housing portion 94 and a proximal housing portion 96. These housing portions are held together by a slotted tube 98 extending axially within the threaded handle.

[0031] A slider 100 is affixed to the proximal end of sheath 32. Slider 100 includes a threaded ring 102 encircling slotted tube 98, and an inner body 104 which rides within the slotted tube. Threaded ring 102 is affixed to inner body 104 by glue, tabs protruding radially from the inner body, tabs protruding radially inwardly from the thread ring, or other mechanical attachment device and the like. Regardless, some structure of slider 100 extends radially through the slots of slotted tube 98, so that the slotted tube rotationally restrains slider 100.

[0032] A reinforcing rod 106 extends distally from proximal portion 96 of housing 50. Reinforcing tube 106 extends through slider 100 to near the distal end of housing 50, and is slidingly received in the lumen of sheath 32. Connector 56 is couplable to a proximal fitting 108. Connector 56 is affixed to shaft 34, so that housing 50 maintains axial alignment between outer tube 54 and shaft 34 when the connector 56 is attached to proximal fitting 108. Reinforcing tube 106 prevents buckling of shaft 34 as slider 100 moves proximally.

[0033] Sheath 32 is withdrawn proximally by rotating handle 52 relative to housing 50. As threaded ring 102 of slider 100 engages internal threads 92 of handle 52, and as slotted tube 98 rotationally restrains slider 100 within housing 50, rotation of the handle pulls the slider and attached graft cover axially as shown. In this embodiment, internal threads 92 are constant along the length of handle 52, so that a particular displacement of the handle relative to the housing will effect a consistent axial displacement of the slider regardless of the slider's position. Such constant internal threads will generally have a pitch of between about 0.125 and 0.250, providing a total mechanical advantage in a range from about 4:1 to 3:1 between handle 52 and sheath 32. As will be described hereinbelow, the threads will often have two or more leads, so that the distance between adjacent threads may be 1/2 (or less) the thread pitch.

[0034] A variable displacement delivery system 110 is illustrated in Figs. 10 and 11. Variable pitch delivery system 110 includes many of the same components described above, but makes use of a handle 112 having variable pitch internal threads 114. Variable threads 114 have a relatively small pitch adjacent the distal end of handle 112 so that each rotation of the handle moves sheath 32 proximally a relatively small axial distance during the initial phases of deployment. This provides an increased mechanical advantage between the handle and the sheath, helping the physician to overcome the large static frictional forces between the prosthesis and the surrounding sheath. This enhanced mechanical advantage also helps overcome any invagination of the prosthetic frame into the surrounding sheath material.

As a result, the distal end of the prosthesis (which is deployed first) will be very gradually released, allowing the physician to verify the accuracy of the deployment position as the prosthesis initially engages the surrounding body lumen. These distal threads will generally have a pitch of between about 0.125 and 0.375, providing a mechanical advantage in the range from about 4:1 to about 2.5:1.

[0035] While it is possible to use a constant thread delivery system having a relatively small pitch, this requires repeated rotation of the handle for a considerable amount of time. Additionally, frictional forces between the prosthesis and surrounding sheath decrease once the static frictional forces have been overcome and the sheath begins to move, as dynamic frictional forces are typically lower than static frictional forces. Additionally, as more and more of the prosthesis is released from the surrounding sheath, the total normal force between the prosthesis and the sheath decreases. This acts to further reduce the friction of deployment. The expanded portion of the prosthesis may even help pull the remaining compressed portion axially as the prosthesis expands within the surrounding runners. Finally, once an end of the prosthesis has firmly engaged the surrounding body lumen, the relationship between the prosthesis and the surrounding body lumen is largely set, so that deployment can proceed safely at a more rapid rate. As a result of all these interactions, it is generally desirable to decrease the mechanical advantage between handle 112 and sheath 32 as the sheath moves from a distal position 118 over the prosthesis to a proximal position 120, at which the prosthesis is fully deployed.

[0036] The use of variable threads 114 and the interaction between handle 112, slider 100, and the slotted tube 98 can be understand with reference to Figs. 12-17. Fig. 12 illustrates a mandril 122 over which handle 114 is molded to impose variable threads 114. The handle will often be molded in two halves over mandrel 122, with the two halves bonded axially. Mandrel 122 includes external threads 124 which vary in pitch along the axial length of the mandrel. Preferably, threads 124 comprise multi-lead threads having two or more helical thread elements. As a result, a distance 126 between adjacent thread elements is only one half of the pitch 128 at the distal end of mandrel 122. The use of multi-lead threads allows multiple elements to extend axially from the slider to engage the surrounding threads, and thereby enhances the stability of the slider.

[0037] As described above, distal pitch 128 is significantly less than a proximal pitch 130, so that rotation of the handle at a constant speed results in increased axial speed of the sheath relative to the prosthesis. Each rotation of handle 112 preferably moves sheath 32 an axial distance of about 0.25 inches when sheath 32 is adjacent covered position 118, while this same rotation of the handle preferably moves the sheath an axial distance of about 0.75 inches when the sheath is adjacent the deployed position 120. In other words, in the exemplary embodiment distal pitch 128 is about 0.25 inches, while proximal pitch 130 is about 0.75 inches. The threads may vary linearly between the proximal and distal ends (as illustrated in Fig. 12), or may vary substantially step-wise as illustrated in Fig. 10. Still further alternatives are possible, such as a quadratic variation in pitch along the axial length of the threads. An preferred delivery system using the above described variable pitch, mechanical advantage is fully described in copending application Serial No. 08/898,997, filed July 24, 1997, which is herein incorporated by reference for all purposes.

[0038] As can be seen in Figs. 13 through 15, slider 100 may be formed by bonding a finned inner body 132 to an outer ring 134. Outer ring 134 includes opposed pins 136 which extend into the two helical elements of internal variable threads 114 in handle 112. The use of pins rather than external threads on outer ring 134 prevents binding between slider 100 and the handle when the pitch of the threads changes. Also illustrated in Fig. 13 is the interaction of slotted tube 98 and slider 100, whereby the slotted tube rotationally restrains the slider when handle 112 rotates. In some embodiments, slider 100 may include only an inner or outer body. For example, an inner body may have pins which extend through the slotted tube and into variable threads 114, or an outer body may have fins extending into the slotted tube. The use of inner and outer bodies may enhance the stability of the slider to prevent binding.

[0039] The handle of delivery system 30 or variable displacement delivery system 110 may be rotated in either an unrestricted clockwise and/or counter-clockwise direction. During initial deployment of the prosthesis, the catheter is under load because the stent-graft tends to resist deployment due to friction. Because of the radial expansion forces from the prosthesis, the threaded portion of the handle, which translates rotational motion to longitudinal motion, may tend to rotate on its own. In order to restrict inadvertent movement of the delivery system, the handle rotation may optionally be restricted by a uni-directional ratcheting mechanism.

[0040] As shown in Figs. 18 and 19, a delivery system 210 has a handle with a uni-directional ratcheting mechanism. The uni-directional delivery system 210 includes many of the same components described above, but incorporates a handle 212 having ratcheting mechanism 214. The ratcheting mechanism 214 provides for "one-way" rotation of handle 212 during the deployment of the prosthesis. Specifically, the ratchet mechanism is in a driving engagement with sheath 32 in a first direction of handle rotation, which allows handle 212 to advance sheath 32. Ratchet mechanism 214 is simultaneously in a ratcheting relationship, in a second direction of handle rotation, which is opposite to the first direction. Accordingly, the ratchet mechanism allows rotation of handle 212 in a first direction while restraining a second direction of handle rotation, opposite to the

first direction.

[0041] In a preferred configuration, ratcheting mechanism 214 makes use of a pliable, resilient member 216 and a ratchet wheel 218, which are operatively engaged to provide a ratcheting action. The ratcheting mechanism is disposed in a proximal end of delivery system 210, trapped between threaded tube 220 and rear grip 222. What follows is a description of each element of the mechanism.

[0042] Resilient member 216, as illustrated in Fig. 20, resembles two halves of a coil spring 228 which protrude upward from a ring base 230. Preferably, base ring 230 is mounted, as shown in Fig. 21, in a recess provided in the rear portion of housing 50 disposed at the proximal end of threaded tube 220. The resilient member has at least one pawl 232 disposed on a top portion of half coil 228. Alternatively, the resilient member has a plurality of pawls. Preferably, two pawls are disposed on each half coil 228, separated on opposite sides of resilient member 216. Pawl 232 is a device fitted to fit into a notch of, for example, a ratchet wheel to impart forward motion or restrict backward motion. Generally, resilient member or ratchet ring 216 is made of a spring like material, either metal or polymeric, which can be easily formed in for example, a molding or machining process. Alternatively, resilient member 216 may be any type of biasing member, such as a full coil spring, leaf spring or similar device capable of urging pawl 232 into engagement.

[0043] Ratchet wheel 218 is disposed on, or coupled to, a proximal or rear portion of outer tube 54, which extends distally from housing 50 over sheath 32. Ratchet wheel 218 is mounted such that rotation of handle 212 causes the ratchet wheel to rotate. Ratchet wheel 218 has a plurality of serrations 219, typically formed in a ring, which extend proximally to engage pawls 232 on ratchet ring 216. Ratchet wheel 218, as well as serrations 219, can be made of a wide variety of materials, preferably of a material that resists wear due to frictional engagement with another material, such as Teflon® or similar material.

[0044] In operation, rotation of handle 212 causes ratchet wheel 218 to rotate. Resilient member 216 is operative on pawls 232 and urges the pawls into a ratcheting engagement with ratchet wheel 218. Pawls 232 provide a driving engagement with ratchet wheel 218 to allow for rotation of handle 212 in a first direction. Pawl 232 is simultaneously in a ratcheting relationship with ratchet wheel 218, in a second direction opposite the first direction. In this configuration, inadvertent counter-rotation of handle 212 is prevented, which may adversely affect the delivery or positioning of the prosthesis.

[0045] Counter-rotation, or else free rotation, of the handle may be desired, for example, for fine positioning of the prosthesis or else removal of a partially deployed sheath. Accordingly, ratcheting mechanism 214 can be disengaged to allow free rotation of the handle. For this purpose, tabs 226 are included on a perimeter of ratchet ring 216, the tabs extending out radially from ratchet ring 216. When ratchet ring 216 is positioned in rear grip 222, tabs 226 can protrude through a surface portion of rear grip 222, preferably through slots 234. Thus, tabs 226 are made accessible from the outside of rear grip 222.

[0046] In operation, a manual force may be applied to tabs 226 in a proximal direction, forcing the tabs to move down slots 234. At the proximal end of slots 234 are grooves 236 positioned perpendicular to the slots. A torque applied to the tabs will force the tabs into grooves 236, where the tabs can remain parked until removed. By forcing down tabs 226, ratchet ring 216 is compressed, which disengages pawls 232 from serrations 219. In this configuration, handle 212 is free to rotate in any direction.

[0047] When ratchet ring 216 is engaged with serrations 219 and handle 212 is rotated, an audible sound is produced by the disengaging and re-engaging of the pawls with the rotating serrations. The sound signifies to the user that the handle is rotating.

[0048] Generally, delivery system 30 (including housing 50 and actuation mechanism 90) will be formed from inexpensive polymeric materials, and will be undetachable secured together so that the delivery system is disposable after use. In the exemplary embodiment, core shaft 44 comprises a polyester ethylketone (PEEK), while shaft 34 may comprise a high-strength polymer such as PEBAX®. Slider 100 will typically be formed from molded polymers such as polycarbonate, while reinforcing tube 106 and slotted tube 98 may be formed from stainless steel, thermoplastic, or thermoset materials. Handle 112 and housing 50 will also typically comprise molded polymer structures.

[0049] Connector 56 (and the associated fitting at the proximal end of housing 50) is commercially available from Colder Products Company of St. Paul, Minnesota, under model number MPC 170-04T. Those skilled in the art should recognize that delivery system 30 will typically be substantially sealed to maintain hemostasis, typically using o-rings to seal between reinforcing tube 106 and sheath 32, as well as between reinforcing rod 106 and shaft 34. The reinforcing rod will typically extend substantially through housing 50, but will not extend distally significantly beyond the housing to allow the delivery system to flex within the body lumen. As illustrated in Fig. 11, such flexibility may be enhanced by decreasing the diameter of sheath 32 proximally of the prosthesis.

[0050] While the exemplary embodiment of the present invention has been described in substantial detail by way of example and for clarity of understanding, a number of adaptations, modifications, and changes will be obvious to those skilled in the art. Hence, the scope of the present invention is limited solely by the appended claims.

Claims

1. A delivery system (30) for use with a tubular endoluminal prosthesis (10), the delivery system (30) comprising:

   a sheath (32) having a proximal end (38), a distal end (40), and a lumen (36), capable of receiving the prosthesis (10) near the distal end (40);
   a member in the lumen (36) of the sheath (32), the member expelling the prosthesis (10) from the lumen (36) as the sheath (32) moves from a first position (118) to a second position (120) relative to the member;
   an actuation mechanism (90) engaging the member and coupling a handle (52) to the sheath (32); and
   a uni-directional mechanism (214) operatively associated with the actuation mechanism (90), the uni-directional mechanism (214) capable of preventing movement of the sheath (32) toward the first position.

2. A delivery system as claimed in claim 1, wherein the uni-directional mechanism (214) allows rotation of the handle (52) in a first direction while restraining a second direction of handle rotation opposite to the first direction.

3. A delivery system as claimed in claim 1, wherein the uni-directional mechanism (214) drivingly engages the sheath (32) when turning the handle (52) in a first direction, the uni-directional mechanism (214) releasably preventing a second direction of handle rotation opposite to the first direction.

4. A delivery system as claimed in claim 1, wherein said uni-directional mechanism (214) comprises:

   a resilient member (216) having at least one pawl (232); and
   a serration ring (219), the serration ring engaging the at least one pawl (232) in a ratcheting relationship;
   wherein the resilient member (216) is operative on the at least one pawl (232) for urging the at least one pawl (232) into the engagement.

5. A delivery system as claimed in claim 4, wherein the at least one pawl (232) drivingly engages the serrations (219) in a first direction of handle rotation, the pawl (232) being in the ratcheting relationship with the serrations (219) in a second direction of handle rotation opposite to the first direction.

6. A delivery system as claimed in claim 1, wherein the uni-directional mechanism (214) is biased to an engaged position.

7. A delivery system as claimed in claim 1, wherein the uni-directional mechanism (214) is biased to a disengaged position.

8. A delivery system as claimed in claim 1, wherein the uni-directional mechanism (214) produces an audible sound.

9. A delivery system as claimed in claim 1, wherein the actuation mechanism (90) has a mechanical advantage which varies as the sheath 32) moves between the first position (118) and the second position (120).

10. A delivery system as claimed in claim 9, wherein the mechanical advantage when the sheath (32) is adjacent the first position (115) is adapted to overcome static frictional forces between the prosthesis (10) and the sheath (32), and wherein the mechanical advantage when the sheath (32) is adjacent the second position (120) overcomes dynamic frictional forces which are smaller than the static frictional forces, and enhances the speed of expelling the prosthesis (10) from the sheath (32).

11. A delivery system as claimed in claim 1, wherein the actuation mechanism (90) comprises threads (114) defining an axis, and wherein a pitch of the threads (114) varies along said axis of the threads (114) to provide a mechanical advantage.

12. A prosthetic delivery system (30) for use with a radially expandable tubular endoluminal prosthesis (10), the delivery system (30) comprising:

   a sheath (32) having a proximal end (38), a distal end (40), an axis there-between, and a lumen (36) capable of receiving the prosthesis (10) near the distal end (40);
   a member in the lumen (36) for expelling the prosthesis (10) from the lumen (36) as the sheath (32) moves from a first position (118) to a second position (120) relative to the member;
   an actuation mechanism (90) engaging the member comprising threads (114), wherein a pitch of the threads (114) varies along an axis of the threads (114), the actuation mechanism coupling the sheath (32) to a handle (112), the handle (112) rotatable about an axis substantially parallel to the axis of the sheath (32) to effect movement of the sheath (32) from the first position (118) to the second position (120); and
   a uni-directional mechanism (214) associated with the actuation mechanism (90) comprising:
   a resilient member (216) having at least one

pawl (232); and

a serration ring (219), the serration ring engaging the at least one pawl (232) in a ratcheting relationship;

wherein the resilient member (216) is operative on the at least one pawl (232) for urging the at least one pawl (232) into the engagement.

13. A delivery system as claimed in claim 12, wherein a pitch of the threads (114) varies along an axial length of the rotatable handle portion.

14. A delivery system for inserting a tubular endoluminal prosthesis (10) into a patient body (84), the delivery system comprising:

a sheath (32) having a proximal end (38), a distal end (40), and a lumen (36) capable of receiving the prosthesis (10) near the distal end (40);

a member disposed in the lumen (36) for expelling the prosthesis (10) from the lumen (36) as the sheath (32) moves from a first position (118) to a second position (120) relative to the member;

an outer tube (54) disposed over the sheath (32) so that the outer tube remains substantially axially aligned with the member when the sheath (32) moves from the first position (118) to the second position (120);

a serration ring (219) disposed on a portion of the outer tube (54); and

a resilient member (216) having at least one pawl (232), the resilient member (216) operative on the at least one pawl (232) for urging the at lest one pawl (232) into a ratcheting relationship with the serration ring (219).

15. An improved delivery system for inserting a tubular endoluminal prosthesis (10) into a patient body (84) of the type comprising a sheath (32) having a proximal end (38), a distal end (40), and a lumen (36) capable of receiving the prosthesis (10) near the distal end ((40); a member disposed in the lumen (36) for expelling the prosthesis (10) from the lumen (36); and an actuation mechanism (90) engaging the member and coupling a handle (52) to the sheath (32), the improvement comprising a uni-directional mechanism (214) operatively associated with the actuation mechanism (90) to provide incremental uni-directional movement of the sheath (32), wherein the uni-directional mechanism (214) allows rotation of the handle (52) in a first direction while restraining a second direction of handle rotation opposite to the first direction.

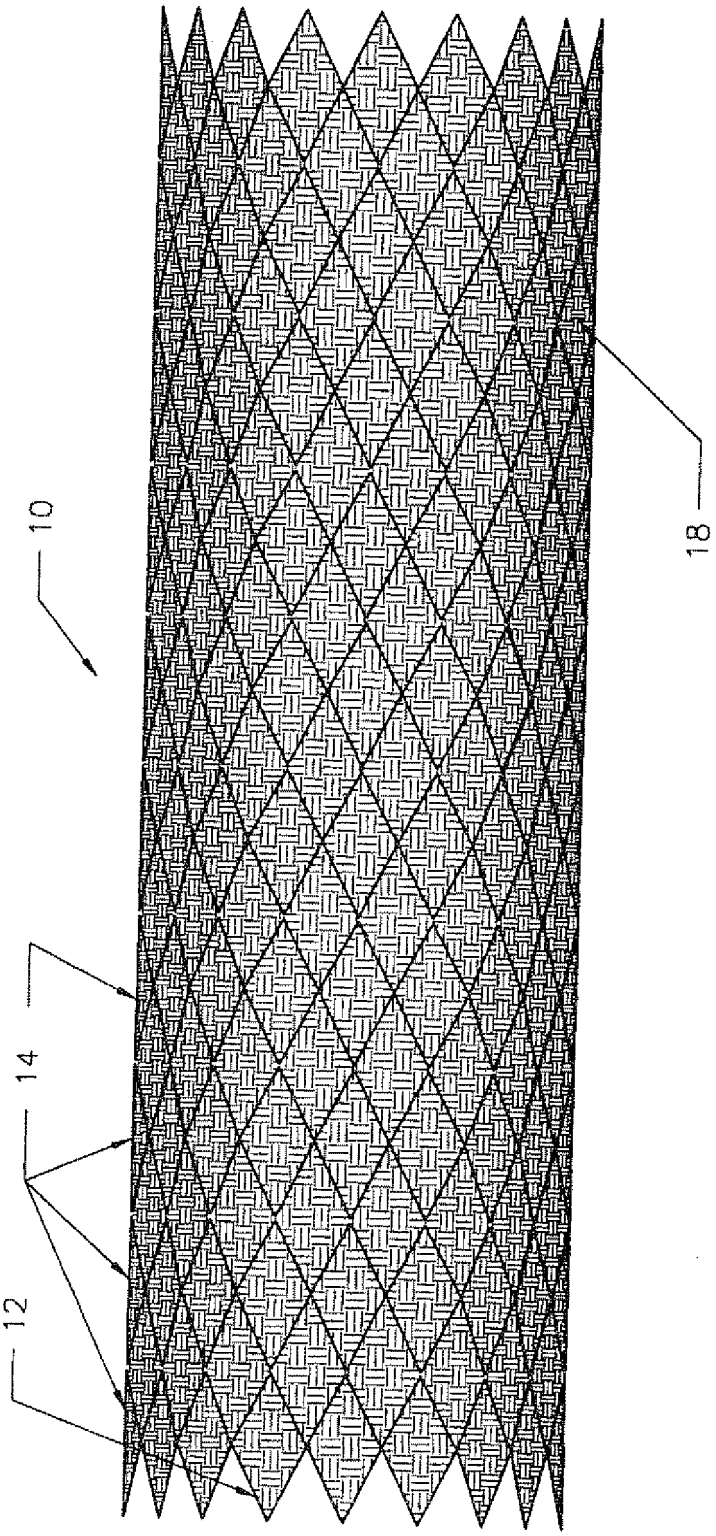


FIGURE 1

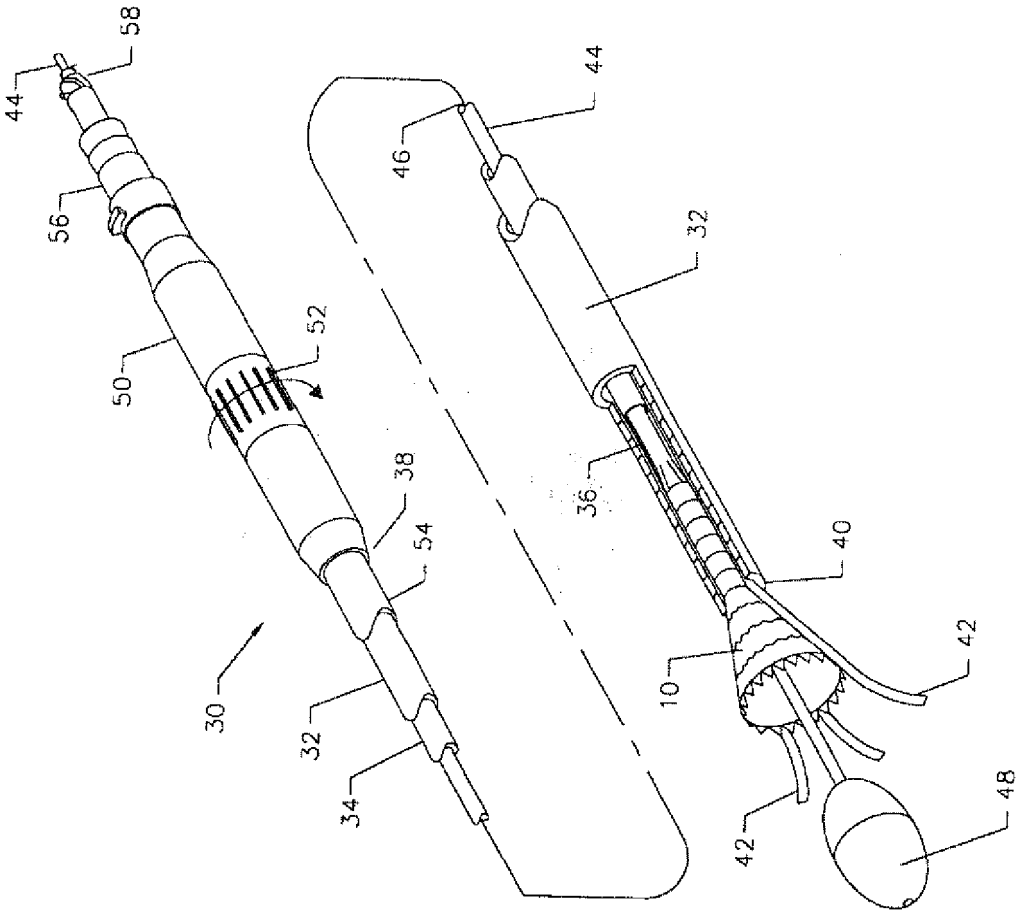


FIGURE 2

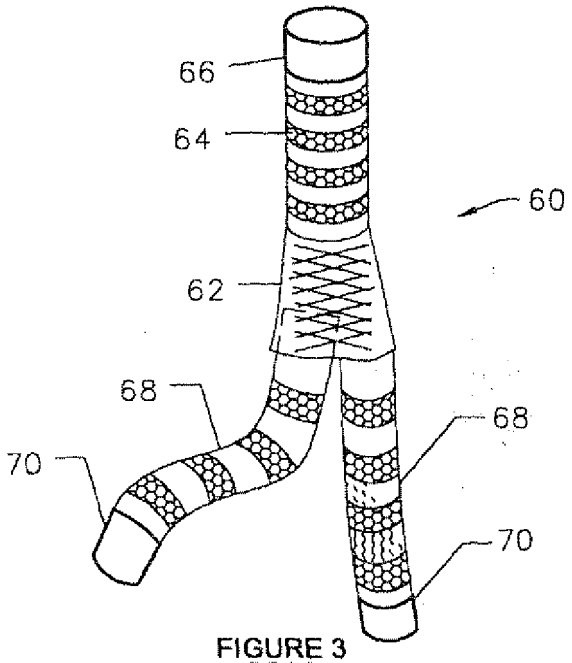


FIGURE 3

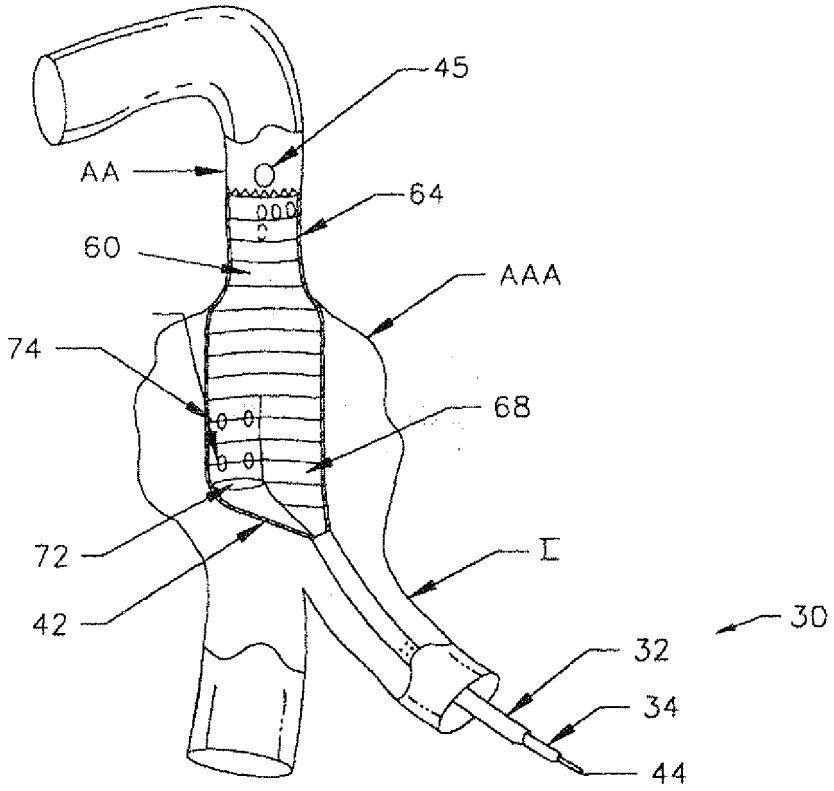


FIGURE 4

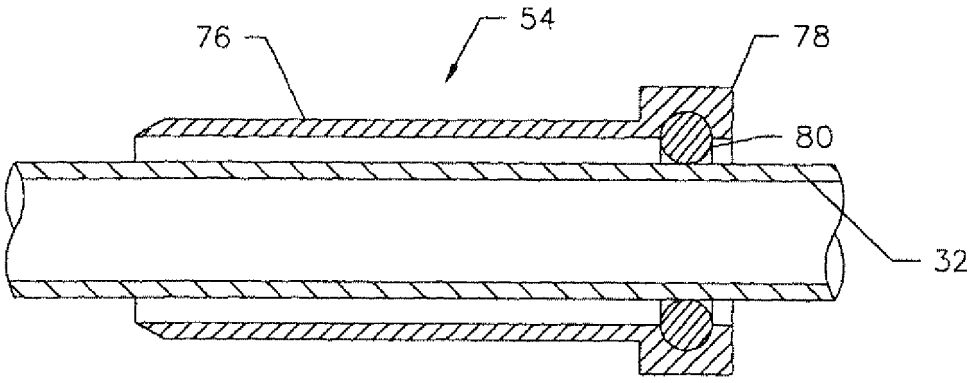


FIGURE 5

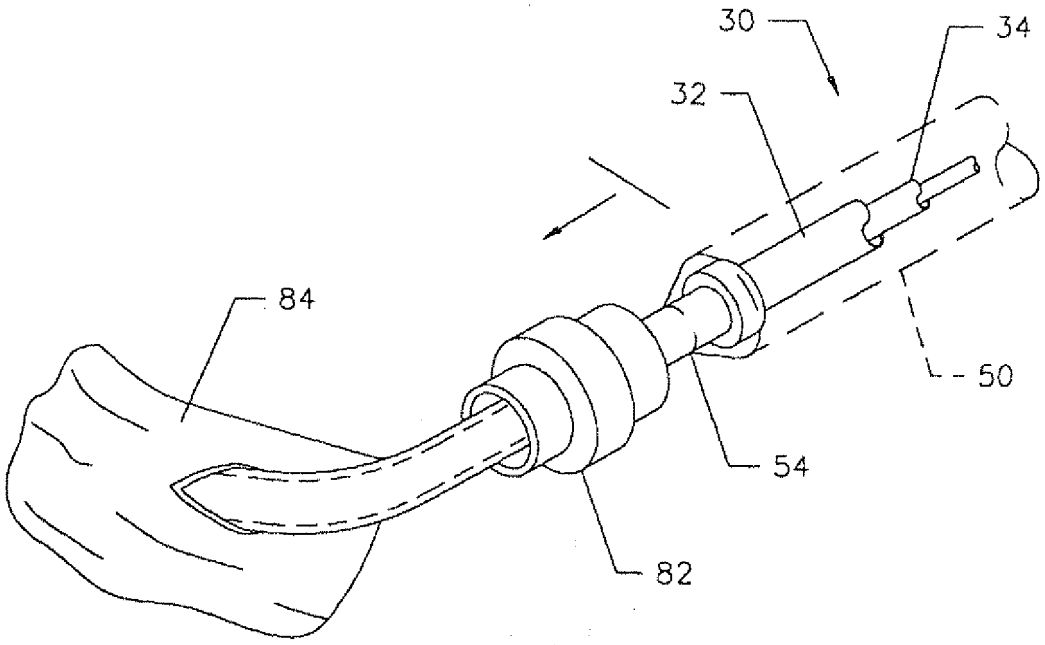


FIGURE 6

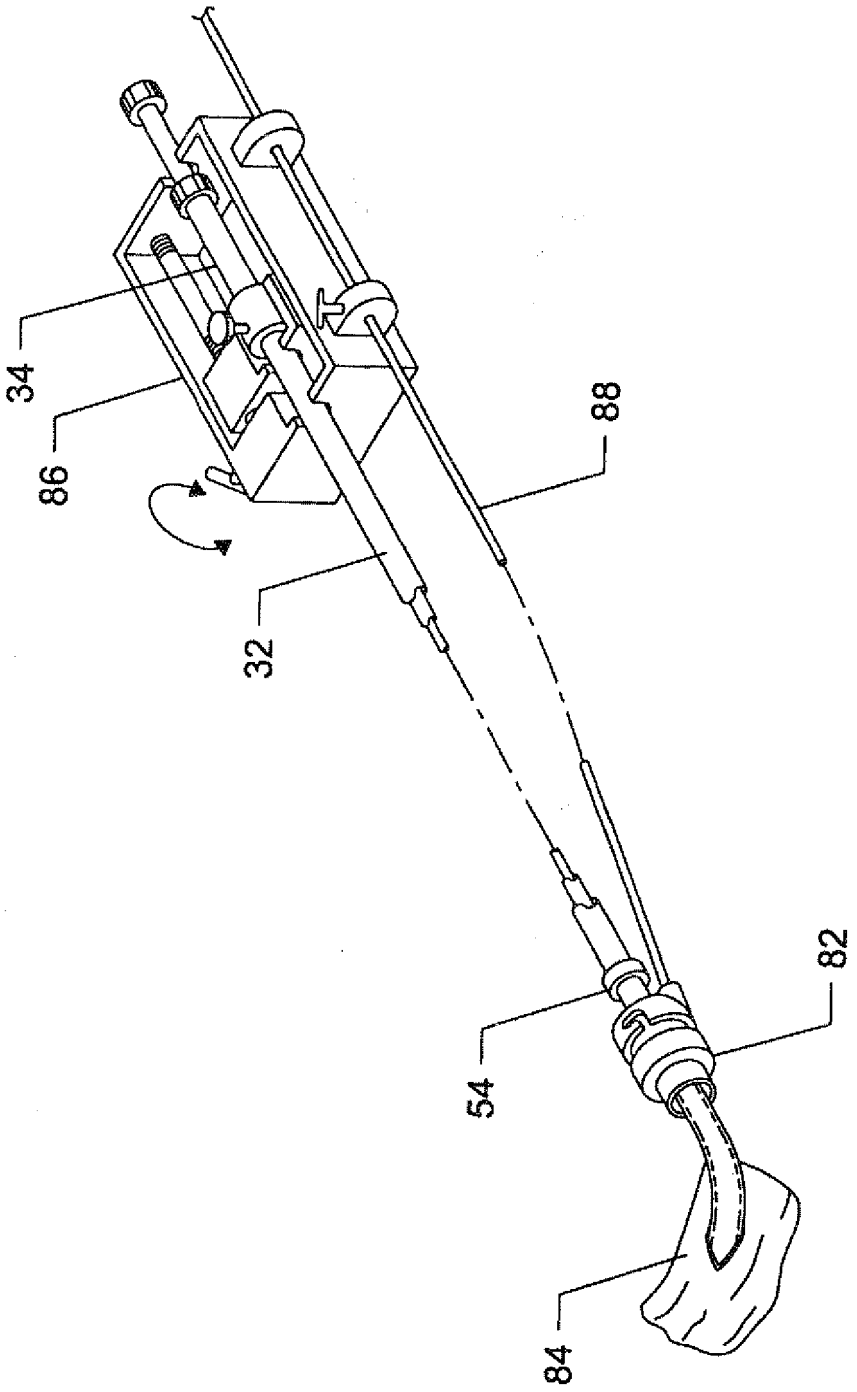
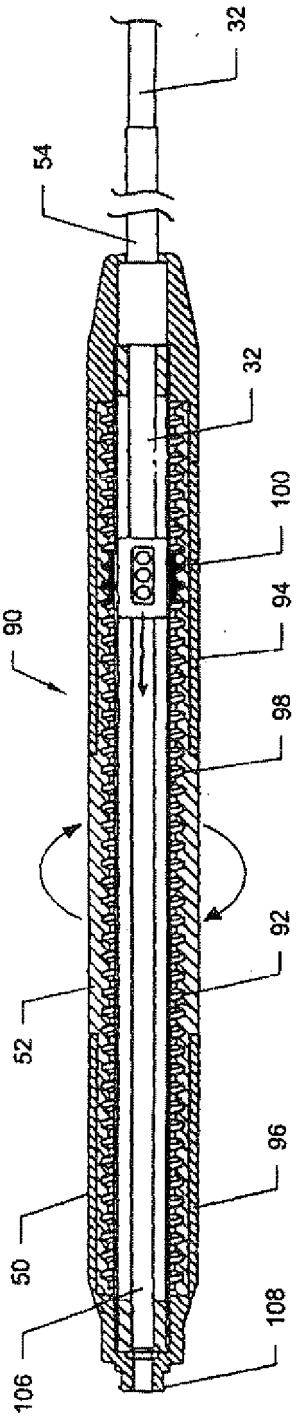


Fig.7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32
100
94
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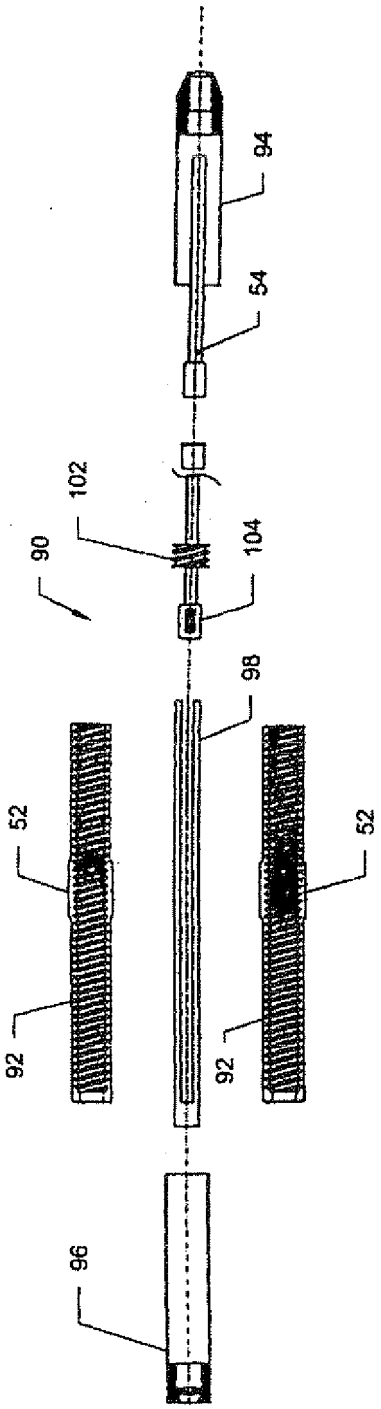
98
92
52
96
50
108
106

Fig. 8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54
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92
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96

Fig. 9

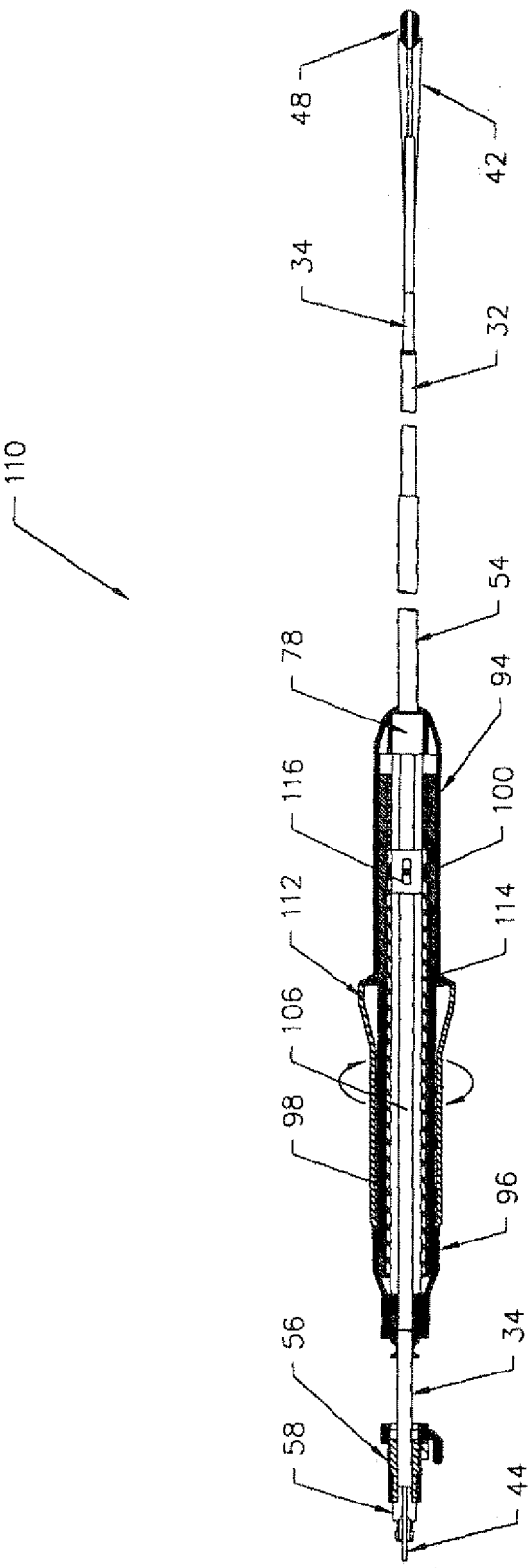

FIGURE 10

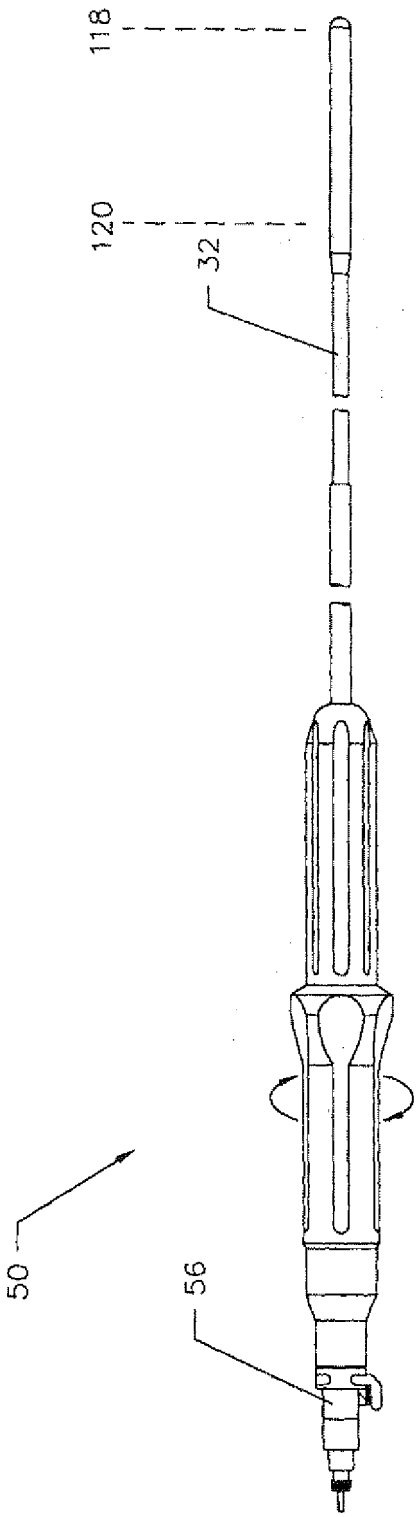

FIGURE 11

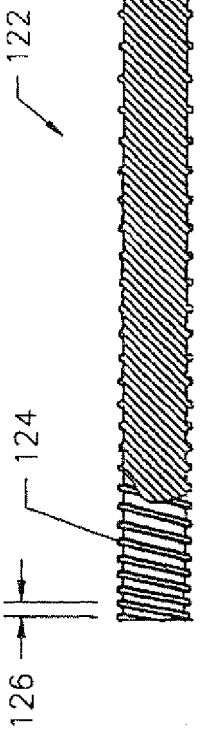

FIGURE 12

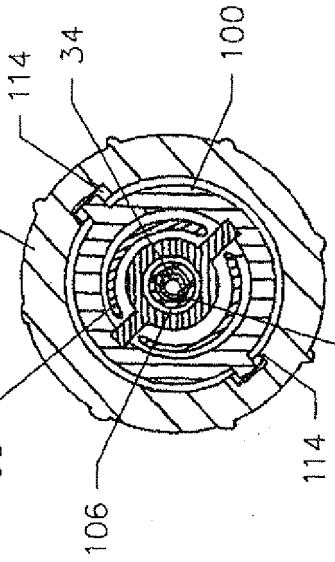

FIGURE 13

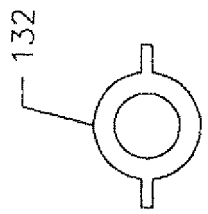

FIGURE 16

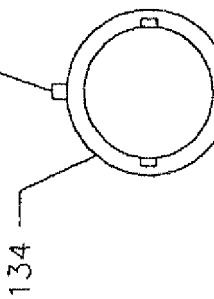

FIGURE 15

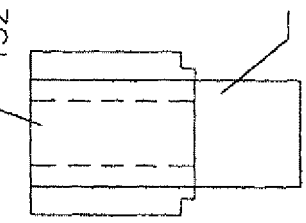

FIGURE 17

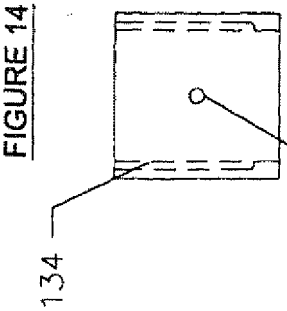

FIGURE 14

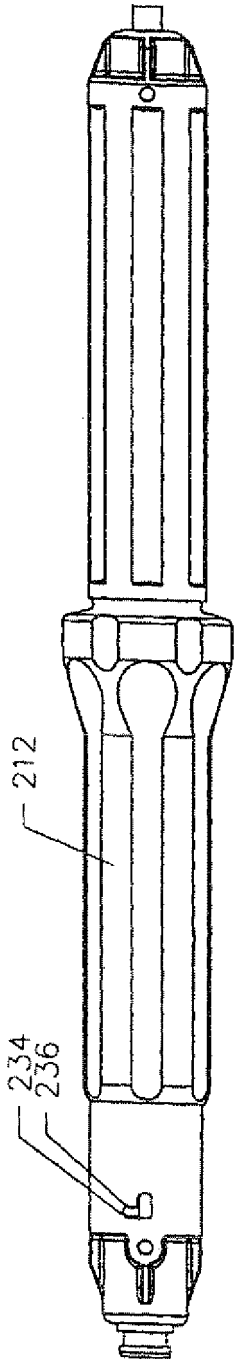

FIGURE 19

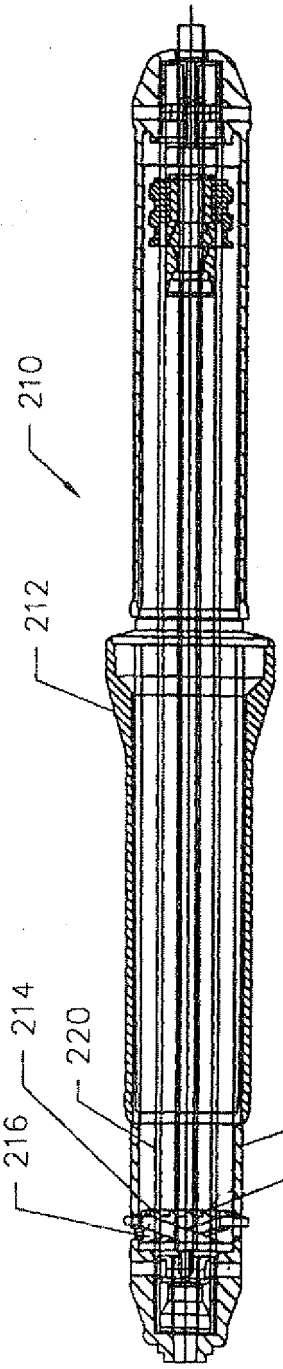

FIGURE 18

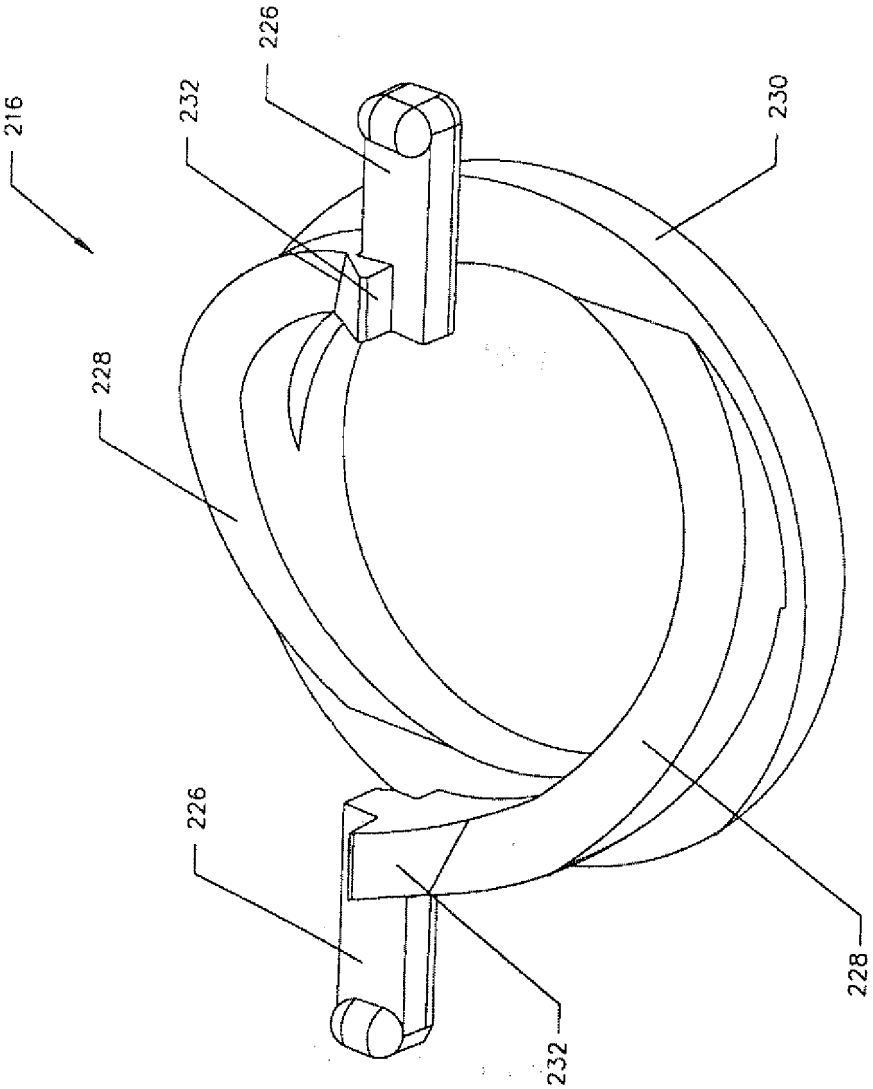

FIGURE 20

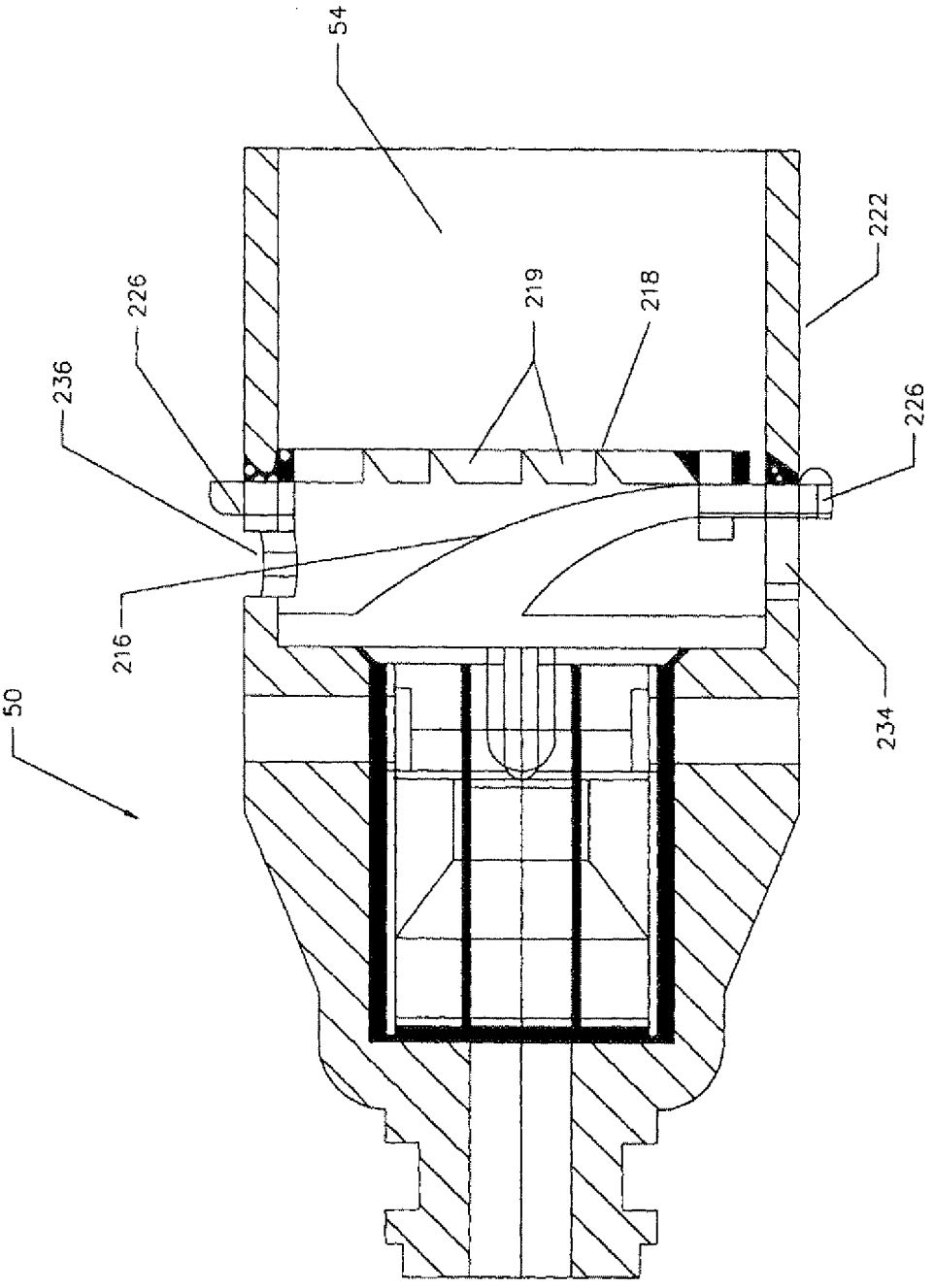

FIGURE 21

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 99 11 8649

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
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Y	US 4 568 335 A (UPDIKE STUART J ET AL) 4 February 1986 (1986-02-04) * column 4, line 1 - line 15 * * column 7, line 43 - column 8, line 50 * * claims; figures 1,8-13 *	1-15	
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TECHNICAL FIELDS SEARCHED (Int.Cl.7)

A61F
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	18 January 2000	Kuehne, H-C

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